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| 10/702,319 | 11/06/2003 | Ranjan Perera | ARBG-004/07US<br>307197-2038 | 7997 |

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| EXAMINER | |
|---|---|
| QIAN, CELINE X | |
| **ART UNIT** | **PAPER NUMBER** |
| 1636 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/702,319 | PERERA ET AL. | |
| | Examiner | Art Unit | |
| | CELINE X. QIAN | 1636 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *08 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *22-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-39* is/are rejected.

7)☒ Claim(s) *24* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

Claims 22-39 are pending in the application.

This Office Action is in response to the Amendment filed on 12/5/08.

### *Response to Amendment*

All previous rejections not reiterated in this office action are considered withdrawn.

### *Specification*

The specification is objected to because the attempt to incorporate subject matter into this application by reference to the provisional application 60/425087 is ineffective because the does not comply with 37 CFR 1.57 for comprising essential material.

The incorporation by reference will not be effective until correction is made to comply with 37 CFR 1.57(b), (c), or (d). If the incorporated material is relied upon to meet any outstanding objection, rejection, or other requirement imposed by the Office, the correction must be made within any time period set by the Office for responding to the objection, rejection, or other requirement for the incorporation to be effective. Compliance will not be held in abeyance with respect to responding to the objection, rejection, or other requirement for the incorporation to be effective. In no case may the correction be made later than the close of prosecution as defined in 37 CFR 1.114(b), or abandonment of the application, whichever occurs earlier.

Any correction inserting material by amendment that was previously incorporated by reference must be accompanied by a statement that the material being inserted is the material incorporated by reference and the amendment contains no new matter. 37 CFR 1.57(f).

In the response filed on 12/8/08, Applicants submitted amendment to the specification, including drawings Figure 6-15, addition of example 4, and a new sequence listing that included SEQ ID NO: 130-137. However, this objection is maintained because the amendment is not accompanied by the required state as highlighted above. It would be remedial to submit the amendment with the proper statement.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 22-37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The written description requirement is set forth by 35 U.S.C. 112, first paragraph which states that the: "*specification* shall contain a written description of the invention...[emphasis added]." The written description requirement has been well established and characterized in the case law. A specification must convey to one of skill in the art that "as of the filing date sought, [the inventor] was in possession of the invention." See *Vas Cath v. Mahurkar* 935 F.2d 1555, 1560 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). Applicant may show that he is in "possession" of the invention claimed by describing the invention with all of its claimed limitations "by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed

invention." See *Lockwood v. American Airlines Inc.* 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

In analyzing whether the written description requirement is met, it is first determined whether a representative number of species have been described by their complete structure. Next, it is determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics. Claim 22 recites a functional vascular tissue specific *E. grandis* cOMT promoter that comprises 1525-1643 of SEQ ID NO: 113, whereas claim 23 recites specific fragments from SEQ ID NO:12, SEQ ID NO:60, nucleotides 1-1643 of SEQ ID NO:113, nucleotides 1019-1643 of SEQ ID NO: 113. The claimed genus of nucleic acids encompasses a large number of sequences of various lengths and various structures (sequence) of the *E. grandis* cOMT gene. The instant specification only discloses that the sequences from the 5'UTR of cOMT gene, particularly, a 1700 nucleotide from SEQ ID NO: 113 and the sequence of SEQ ID NO: 12, which have the vascular tissue specific regulatory function. The specification fails to disclose whether other fragments of SEQ ID NO: 113 or the sequence recited in claim 22 and 23 that have the claimed vascular tissue specific regulatory function. Moreover, the specification does not disclose what necessary element is required for the claimed function. The instant specification also fails to whether this fragment of 1019-1643, 1525-1643 of SEQ ID NO:113 has vascular specific promoter activity. Claims 24-37 depends on claims 22 and 23, which lack sufficient description for same reason. As such, the specification fails to provide adequate support for the claimed invention. Therefore, in view of the claimed broad genus, and the limited

disclosure of the instant specification, the description in the instant specification is not adequate to support the claimed genus.

In response to the written description rejection, the response filed on 10/30/07 indicates that the claimed fragments has adequate description in the provisional application 60/425,087. In the response filed on 12/8/08, Applicants submitted amendment to the specification, including drawings Figure 6-15, addition of example 4, and a new sequence listing that included SEQ ID NO: 130-137. However, according to MPEP, Essential material" is defined >in 37 CFR 1.57(c)< as that which is necessary to (1) provide a written description of the claimed invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and set forth the best mode contemplated by the inventor of carrying out the invention as required by the first paragraph of 35 U.S.C. 112, (2) describe the claimed invention in terms that particularly point out and distinctly claim the invention as required by the second paragraph of 35 U.S.C. 112, or (3) describe the structure, material, or acts that correspond to a claimed means or step for performing a specified function as required by the sixth paragraph of 35 U.S.C. 112. In any application that is to issue as a U.S. patent, essential material may only be incorporated by reference to a U.S. patent or patent application publication. Since the material provided in 60/425,087 is necessary to provide a written description of the claimed invention, it is considered to be "essential material." The incorporation of essential material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to

include the material incorporated by reference, if the material is relied upon to overcome any objection, rejection, or other requirement imposed by the Office. The amendment must be accompanied by a statement executed by the applicant, or a practitioner representing the applicant, stating that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter. 37 CFR 1.57(f). In the response filed on 12/8/08, this statement is missing. Therefore, the requirement is not satisfied. This rejection is maintained because the incorporation by reference is improper according to the 37CRF1.57. It would be remedial to submit the above amendment with the proper statement.

The newly presented claim 22 lack sufficient description from the instant specification because of the recitation of "an isolated polynucleotide comprising a sequence of nucleotides 1525-1643 of SEQ ID NOO 113 comprising a functional vascular tissue specific E. grandis cOMT promoter." Even the material incorporated by reference from 60/425,087 is considered proper, this claimed genus of vascular tissue specific promoter still lack sufficient from the disclosure as filed. The recitation of "a sequence of" means that the claimed genus of promoter encompasses fragments of 1525-1643 of SEQ ID NO: 113 in varying length ranging from 2-119 in length which possesses vascular specific promoter activity. However, according to the disclosure of the instant specification, the 119 bp fragment of 1525-1643 of SEQ ID NO: 113 is the shortest sequence that still possesses such activity. As such, the specification fails to describe the claimed genus of nucleotides by a representative number of species by their complete structure or other identifying characteristics. Therefore, the disclosure does not satisfy the written description requirement. Claims 23-37 also lack sufficient description

because they depend on claim 22. It would be remedial to change language to "the nucleotide sequence" instead.

Regarding claim 32, the claim recites the polynucleotide of claims 22-24 to be inserted in a genetic construct in direct or inverted repeat. The polynucleotide of claims 22-24 are drawn to fragments of SEQ ID NO: 113 which has functional vascular specific promoter activity. As discussed above, the specification, incorporating the disclosure of 60/425,087, discloses specific fragments of SEQ ID NO: 113, SEQ ID NO: 130-134 have the claimed promoter activity. However, the specification does not disclose whether direct or inverted repeat of such fragments still retain the claimed promoter function. The prior art does not teach whether such direct or inverted repeat have the claimed promoter function. In fact, the prior art teaches that the inverted repeat of a promoter do not possess the same promoter activity in the sense direction unless it is an enhancer element. As such, the specification does not describe the claimed genus of direct or inverted repeat of the fragments of SEQ ID NO: 113 claimed in claims 22-24 that has promoter function. The specification thus fails to describe the claimed genus of nucleotides by a representative number of species by their complete structure or other identifying characteristics. Therefore, the disclosure does not satisfy the written description requirement.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 38 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to: (a) the nature of the invention; (b) the breadth of the claims; (c) the state of the prior art; (d) the amount of direction provided by the inventor; (e) the existence of working examples; (f) the relative skill of those in the art; (g) whether the quantity of experimentation needed to make or use the invention based on the content of the disclosure is "undue"; and (h) the level of predictability in the art (MPEP 2164.01 (a)).

**The nature of the invention**

The claim is drawn to an isolated polynucleotide sequence comprising a sequence selected from the group of: a polynucleotide comprising a 20-600 mer of SEQ ID NO: 12, 60, or nucleotides 1-1643 of SEQ ID NO: 113.

**The teaching of the specification and the breadth of the claim**

The instant specification teaches SEQ ID NO: 12, 60 and 1-1643 of SEQ ID NO: 1643 are promoter from cOMT gene of *E. grandis* that directs vascular specific promoter function. However, the specification does not disclose fragments as short as 20-mer which also possess such activity. The claimed scope is broad because it encompasses any fragments ranging from 20-600 of the claimed sequences which may or may not have

promoter activity. Although the specification teaches the sequences of SEQ ID NO: 12, 60 and 113, a skilled artisan would not know how to use said fragments.

**The state of prior art and the level of predictability in the art**

The state of art at the time of filing is silent on the utility for the claimed fragments. The state of art at the time of filing does not teach any fragments of varying length from a known promoter would automatically have a known utility. As such, the skilled artisan would have to rely on the teaching of the specification to make and use the invention as claimed. Since the specification does not teach how to use such 20-600mer except being part of a promoter, one of skilled in the art would have to engage in undue experimentation to use the claimed fragments. Therefore, the claimed fragments of SEQ ID NO: 12, 60 and 113 is not enabled by the instant specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 23, 25-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 23, the recitation of "the isolated polynucleotide of claim 22, wherein the nucleotide comprises a sequence from the group consisting of…" renders the claim indefinite because it is unclear whether the claimed polynucleotide comprises a sequence within 1525-1643, and additionally a sequence selected from the recited group, or just a sequence from the recited group. Proper clarification is required.

Claims 25-37 are rejected for same reason because they depend on claim 23.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 39 is rejected under 35 U.S.C. 102(b) as being anticipated by AAC62810 (2/2/01).

The claim is drawn to an isolated polynucleotide sequence comprising a sequence selected from the group consisting of: a 180 mer, 220-mer...600-mer of SEQ ID NO: 113. Since SEQ ID NO: 113 is first disclosed in 10/137,036, which has an effective filing date of 4/30/02, the priority date of this claim is this date. The sequence of AAC62810 comprises 1662 bp polynucleotide from SEQ ID NO: 113. Therefore, it anticipates the claimed invention.

### *Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a

nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 22-39 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 7365186. Although the conflicting claims are not identical, they are not patentably distinct from each other because they overlap in scope that they are both directed to isolated polynucleotide that confers vascular specific gene expression in a plant cell. The polynucleotide sequence of SEQ ID NO: 1-6 in the '186 patent, and functional fragments thereof, are part of the sequence contained in SEQ ID NO: 113, and they direct vascular specific gene expression in plant cells. Since the '186 patent discloses in the preferred embodiments of using the claimed promoter, functional fragments thereof to generate transgenic plant that can identify genes responsible for a desired function based on the increase or decrease in lignification (see [32]-[36] of the patent), claims 35-37 of the instant application are obvious in view of such teaching. Therefore, claims 22-39 are rejected for double patenting.

***Claim Objections***

Claim 24 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 22 is drawn to an isolated polynucleotide comprising a sequence of nucleotide 1525-1643 of SEQ ID NO:

113, whereas claim 24 is drawn to an isolated polynucleotide comprising any of the sequence of SEQ ID NO: 113. As such, the scope of claim 24 is broader than claim 22, and fail to further limit claim 22.

***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CELINE X. QIAN whose telephone number is (571)272-0777. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Celine X Qian /
Primary Examiner, Art Unit 1636